

REMARKS

In the Final Office Action, pending claims 45-47 are rejected. Applicants have cancelled claims 45 and 46 by this amendment and added new claims 48 and 49. Accordingly, claims 47 – 49 are currently pending in this application.

Applicants note that claims 45 and 46 were depending from a cancelled claim. As a result, Applicants have cancelled claims 45 and 46 and reintroduced them as claims 48 and 49 which depend from independent claim 47. No new matter is introduced by these amendments. As such, Applicants request entry of the new claims.

A. Rejection under 35 U.S.C. §112, second paragraph

Claims 45 and 46 are rejected under 35 U.S.C. §112, second paragraph as being “indefinite because the claims are dependent claims of a cancelled claim, and the metes and bounds of the claim cannot be ascertained.” Claim 47 is rejected as “indefinite because of the use of the term “a fragment”.” The Office Action states, “it is not clear which fragment of HMGI is, e.g., whether this fragment has the same biological function as HMGI.”

With respect to claims 45 and 46, Applicants have cancelled these claims and have reasserted them as new claims 48 and 49. New claims 48 and 49 depend from independent claim 47. Thus, the ‘metes and bounds’ of new claims 48 and 49 can be ascertained and are not indefinite. Accordingly, Applicants request that the rejection under §112, second paragraph be withdrawn.

Applicants respectfully traverse the rejection of claim 47 under 35 U.S.C. §112, second paragraph. HMGI is the architectural component of the enhanceosome (transcription enhancer complex), so it must interact with multiple proteins along with DNA. Thus, theoretically, any compound that binds to HMGI, regardless of what region it binds to, could disrupt this interaction.

An inhibitor may function by binding a seemingly innocuous region of the protein and interfering with protein folding or preventing formation of the necessary tertiary structure. For instance, a protein containing two protein-binding regions connected by a hinge region might not function properly if a compound binds to the hinge region and prevents it from moving into the necessary binding conformation. In addition, a compound binding to a nonfunctional region of HMGI could interfere with protein or DNA binding by a steric interference, if the protein is folded in such a way that the compound binding site is directly next to the DNA or protein binding site. Thus, claim 47 is not limited to compounds that bind functional domains of HMGI. In line with this analysis, the term “a fragment” is not limited to sequences possessing the same biological activity of HMGI or that contain DNA or protein binding domains. Instead, the term “a fragment” represents any polypeptide with an amino acid sequence identical to any region of the HMGI protein. As a result, Applicants use of the term “a fragment” is not indefinite. Applicants request withdrawal of this rejection accordingly.

B. Rejection under 35 U.S.C. §112, first paragraph

Claim 47 is rejected under 35 U.S.C. §112, first paragraph “as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.” Specifically, it appears that issue is taken with three aspects of the claim. First, the Office Action states, “the specification does not indicate which part of HMGI is the claimed fragment and whether this fragment has the HMGI function or contains a functional domain.” Second, the Office Action states, “there is no description regarding the specific means for measuring the binding affinity.” The Office Action also states, “there is no data indicating the levels of reporter gene expression in the

presence and absence of candidate compound being measured.” The following three factors are cited as being most relevant to this rejection regarding undue experimentation: “the lack of working examples, the amount of direction or guidance presented and the amount of experimentation necessary.”

With respect to the fragments, the Office Action states that “unspecified fragments which do not contain functional domains such as DNA binding domain of HMGI would not accomplish the claimed method.” Based on this statement, the Office Action concludes that “it is necessary to specify the fragments with the biological function of HMGI or with the functional domains of HMGI for the claimed process.” Applicants respectfully traverse. For the reasons previously stated in response to the §112, second paragraph rejection, the fragments need not be limited to sequences that contain functional domains of HMGI. Accordingly, Applicants submit that it is not necessary to specify the fragments with the biological function or with the functional domains of HMGI for the claimed process.

Applicants also respectfully traverse the rejection on the grounds that “there is no description regarding the specific means for measuring the binding affinity.” Section 2164 of the MPEP states in part, “[d]etailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention.” See, MPEP §2164. There are many binding assays involving immobilized proteins, protein fragments, or nucleic acids that are obvious to those skilled in the art. These include, but are not limited to, HPLC, SPR, and microwell plate assays. Accordingly, Applicants submit that those skilled in the art would be able to practice the invention based on Applicants description without undue experimentation.

CONCLUSION

Applicants believe that these amendments and responses are sufficient to overcome all of the rejections in the Office Action. Therefore, a prompt Notice of Allowance of claims 47-49 is respectfully requested. If Applicants can do anything more to assist in the entry of this amendment, Applicants request the Examiner to contact the undersigned at (213) 489-1600.

Dated: September 12, 2001

633 West Fifth Street, Suite 4700
Los Angeles, California 90071-2066
(213) 489-1600

Respectfully submitted,
LYON & LYON LLP

By: 

Michael J. Wise
Reg. No. 34,047